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Wyeth Pharmaceuticals

Excerpt from Report of Clinical Study (Feb. 1, 2001)
Protocol 0600D1-159-EU
Supportive Tables ST9-1 and ST9-2

SUPPORTIVE TABLE ST9-1. NUMBER (%) OF SUBJECTS REPORTING ADVERSE EVENTS

03OCT01 10.26 (DEV)

REPORT 5-5

CLINICAL INVESTIGATION OF VENLAFAXINE ER PROTOCOL 0600-159

NUMBER (%) OF SUBJECTS REPORTING ADVERSE EVENTS

BODY SYSTEM (1)				
ADVERSE EVENT	NONE (N = 20)	Venlafaxine 75 mg (Carbopol) (N = 20)	Venlafaxine 75 mg (Long) (N = 20)	Venlafaxine 75 mg (Short) (N = 20)
ANY ADVERSE EVENT	1 (5.0)	10 (50.0)	5 (25 0)	4 (20 0)
BODY AS A WHOLE	1 (5.0)	0	0	0
ACCIDENTAL INJURY	1 (5.0)	0	0	0
DIGESTIVE SYSTEM	0	10 (50.0)	5 (25 0)	4 (20 0)
NAUSEA	ö	10 (50.0)	5 (25.0)	4 (20.0)

BODY SYSTEM (1)		
ADVERSE EVENT	Venlafaxine 75 mg (Wax (N = 20)) Venlafaxine 75 mg (XR-Capsule) (N = 19)
ANY ADVERSE EVENT	4 (20.0)	7 (36.8)
BODY AS A WHOLE	0	0
ACCIDENTAL INJURY	0	0
DIGESTIVE SYSTEM	4 (20.0)	7 (36 8)
NAUSEA	4 (20 0)	7 (36 8)

SUPPORTIVE TABLE ST9-2. NUMBER (1) OF SUBJECTS REPORTING ADVERSE EVENTS BY SEVERITY AND DRUG RELATIONSHIP INCLUDING IDENTIFICATION OF SUBJECTS

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CLINICAL INVESTIGATION OF VENLAPAXINE ER PROTOCOL 0600-159

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REPORT 5-7

NUMBER (4) OF SUBJECTS REPORTING ADVERSE EVENTS BY SEVERITY(1) AND DRUG RELATIONSHIP(2) INCLUDING IDENTIFICATION OF SUBJECTS

TREATMENT: NONE TOTAL SUBJECTS. 20

BODY SYSTEM (3)		4ILD	10M	ERATE	SEVERE		TOTAL				
ADVERSE EVENT	REL.	NOT REL.	REL.	NOT REL	REL.	NOT REL.	REL.	NOT REL.			
ANY ADVERSE EVENT	0	0	0	0	0	1 (5.0)	0	1 (5 0)			
BODY AS A WHOLE	0	0	0	0	0	1 (5 0)	0	1 (5 0)			
ACCIDENTAL INJURY	0	0	0	0	0	1 (5.0) 001-000002	0	1 (5 0)			

NOTE. (1) - SEVERITY IS REGARDED AS THE MAXIMUM INTENSITY REPORTED FOR THE ADVERSE EVENTS

(2) - DRUG RELATIONSHIP IS REGARDED AS THE MAXIMUM DRUG RELATED EVENT FOR THE EVENT SELECTED BY THE SEVERITY

(3) - BODY SYSTEM TOTALS ARE NOT NECESSARILY THE SUM OF THE INDIVIDUAL ADVERSE EVENTS SINCE A PATIENT MAY

REPORT TWO OR MORE DIFFERENT ADVERSE EVENTS IN THE SAME BODY SYSTEM

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CLINICAL INVESTIGATION OF VENLAFAXINE ER PROTOCOL 0600-159

REPORT 5-7

NUMBER (4) OF SUBJECTS REPORTING ADVERSE EVENTS
BY SEVERITY(1) AND DRUG RELATIONSHIP(2) INCLUDING IDENTIFICATION OF SUBJECTS

TREATMENT: Venlafaxine 75 mg (Carbopol) TOTAL SUBJECTS: 20

BODY SYSTEM (3)	MILD			MOE	ERATE	SEVERE		TOTAL				
ADVERSE EVENT	REL.	NO:	r REL.	REL.	NOT REL.	REL.	NOT REL.	REL.	NOT REL			
ANY ADVERSE EVENT	10	(50.0)	0	0	0	0	0	10 (50 0)	0			
DIGESTIVE SYSTEM	10	(50.0)	o	0	0	0	a	10 (50.0)	0			
NAUSEA .	001- 001- 001- 001- 001- 001- 001-	(50.0) 000001 000002 000004 000006 000007 000008 000009 000010 000016 000018	Q	a	0	Q	Q	10 (50 0)	0			

NOTE: (1) - SEVERITY IS REGARDED AS THE MAXIMUM INTENSITY REPORTED FOR THE ADVERSE EVENTS

^{(2) -} DRUG RELATIONSHIP IS REGARDED AS THE MAXIMUM DRUG RELATED EVENT FOR THE EVENT SELECTED BY THE SEVERITY
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CLINICAL INVESTIGATION OF VENLAFAXINE ER PROTOCOL 0600-159

REPORT 5-7

NUMBER (%) OF SUBJECTS REPORTING ADVERSE EVENTS BY SEVERITY(1) AND DRUG RELATIONSHIP(2) INCLUDING IDENTIFICATION OF SUBJECTS

TREATMENT: Venlafaxine 75 mg (Long)

BODY SYSTEM (3)	MILD			MODERATE				SEVERE	TOTAL				
ADVERSE EVENT	REL.	ı	NOT REL.	REL.		NOT	REL.	REL.	NOT REL.	1	REL.		NOT REL
ANY ADVERSE EVENT	4	(20.0	0	1	(5	. 0)	0	0	0	5	(25	. 0)	0
DIGESTIVE SYSTEM	4	(20.0	0	1	(5	.0)	0	0	o	5	(25	0)	0
NAUSEA	001- 001- 001-	(20.0) 000002 000008 000010 000019	0	001-0		0) 07	0	0	0	5	(25	.0)	0

NOTE: (1) - SEVERITY IS REGARDED AS THE MAXIMUM INTENSITY REPORTED FOR THE ADVERSE EVENTS
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CLINICAL INVESTIGATION OF VENLAFAXINE ER PROTOCOL 0600-159

REPORT 5-7

NUMBER (%) OF SUBJECTS REPORTING ADVERSE EVENTS BY SEVERITY(1) AND DRUG RELATIONSHIP(2) INCLUDING IDENTIFICATION OF SUBJECTS

TREATMENT: Venlafaxine 75 mg (Short)

BODY SYSTEM (3)	MILD		MOD	ERATE	SEVERE		TOTAL			
ADVERSE EVENT	REL. NO	T REL.	REL.	NOT REL.	REL.	NOT REL.	REL.	NOT REL		
ANY ADVERSE EVENT	4 (20.0)	0	0	0	0	0	4 (20.0)	0		
DIGESTIVE SYSTEM	4 (20.0)	0	0	0	0	0	4 (20.0)	0		
NAUSEA	4 (20.0) 001-000002 001-000007 001-000008 001-000010	0	O	0	0	o	4 (20.0)	0		

NOTE: (1) - SEVERITY IS REGARDED AS THE MAXIMUM INTENSITY REPORTED FOR THE ADVERSE EVENTS.

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CLINICAL INVESTIGATION OF VENLAFAXINE ER PROTOCOL 0600-159

REPORT 5-7

NUMBER (%) OF SUBJECTS REPORTING ADVERSE EVENTS BY SEVERITY(1) AND DRUG RELATIONSHIP(2) INCLUDING IDENTIFICATION OF SUBJECTS

TREATMENT: Venlafaxine 75 mg (Wax)

BODY SYSTEM (3)		MILD		MODERATE			SEVERE			TOTAL			
ADVERSE EVENT	REL.	NO.	r REL.	REL.	NOT	REL.	REL.	NOT REL.	ı	REL.	NOT REL		
ANY ADVERSE EVENT	3	(15.0)	0	1	(5.0)	0	0	0	4	(20.0)	0		
DIGESTIVE SYSTEM	3	(15.0)	0	1	(5.0)	0	0	0	4	(20.0)	0		
NAUSEA	· 001-	(15.0) 000002 000008 000009	0	001-0	(5.0) 00007	0	0	0	4	(20.0)	O		

NOTE: (1) - SEVERITY IS REGARDED AS THE MAXIMUM INTENSITY REPORTED FOR THE ADVERSE EVENTS.
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CLINICAL INVESTIGATION OF VENLAFAXINE ER PROTOCOL 0600-159

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REPORT 5-7

NUMBER (%) OF SUBJECTS REPORTING ADVERSE EVENTS BY SEVERITY(1) AND DRUG RELATIONSHIP(2) INCLUDING IDENTIFICATION OF SUBJECTS

TREATMENT: Venlafaxine 75 mg (XR-Capsule)

MILD			MODERATE				SEVERE	TOTAL						
REL.		NOT	REL.	REL.		NOT	REL.	REL.	NOT REL.	- 1	REL.		NOT	REL
6	(31	. 6)	0	1	(5	. 3)	0	0	0	7	(36	.8)	0	
6	(31	.6)	0	1	(5	. 3)	0	0	0	7	(36	. 8)	0	
001-0	0000	9	0				0	0	0	7	(36	8)	0	
001-0	0000	13												
	6 6 001-6 001-6 001-6 001-6	6 (31 6 (31 6 (31 001-0000 001-0000 001-0000 001-0000	6 (31.6) 6 (31.6) 6 (31.6) 001-000009 001-000012 001-000013 001-000015 001-000019	REL. NOT REL. 6 (31.6) 0 6 (31.6) 0 001-000009 001-000012 001-000013 001-000015 001-000019	REL. NOT REL. REL. 6 (31.6) 0 1 6 (31.6) 0 1 6 (31.6) 0 1 001-00009 001-0 001-000012 001-000013 001-000015 001-000019	REL. NOT REL. REL. 6 (31.6) 0 1 (5 6 (31.6) 0 1 (5 001-000009 001-0000 001-000012 001-000013 001-000015 001-000019	REL. NOT REL. REL. NOT 6 (31.6) 0 1 (5.3) 6 (31.6) 0 1 (5.3) 6 (31.6) 0 1 (5.3) 001-000019 001-000017 001-000013 001-000015 001-000019	REL. NOT REL. REL. NOT REL. 6 (31.6) 0 1 (5.3) 0 6 (31.6) 0 1 (5.3) 0 6 (31.6) 0 1 (5.3) 0 001-000009 001-000017 001-000012 001-000013 001-000015 001-000019	REL. NOT REL. REL. NOT REL. REL. 6 (31.6) 0 1 (5.3) 0 0 6 (31.6) 0 1 (5.3) 0 0 6 (31.6) 0 1 (5.3) 0 0 001-000019 001-000017 001-000013 001-000015 001-000019	REL. NOT REL. REL. NOT REL. REL. NOT REL. 6 (31.6) 0 1 (5.3) 0 0 0 6 (31.6) 0 1 (5.3) 0 0 0 6 (31.6) 0 1 (5.3) 0 0 0 001-000009 001-000017 001-000012 001-000013 001-000015 001-000019	REL. NOT REL. REL. NOT REL. REL. NOT REL. [6 (31.6) 0 1 (5.3) 0 0 0 7 6 (31.6) 0 1 (5.3) 0 0 0 7 6 (31.6) 0 1 (5.3) 0 0 7 001-000019 001-000017 001-000013 001-000015 001-000019	REL. NOT REL. REL. NOT REL. REL. NOT REL. REL. 6 (31.6) 0 1 (5.3) 0 0 0 7 (36 6 (31.6) 0 1 (5.3) 0 0 0 7 (36 6 (31.6) 0 1 (5.3) 0 0 0 7 (36 001-000009 001-000017 001-000013 001-000015	REL. NOT REL. REL. NOT REL. REL. NOT REL. 6 (31.6) 0 1 (5.3) 0 0 0 7 (36.8) 6 (31.6) 0 1 (5.3) 0 0 0 7 (36.8) 6 (31.6) 0 1 (5.3) 0 0 7 (36.8) 6 (31.6) 0 1 (5.3) 0 0 7 (36.8) 001-000019 001-000017 001-000013 001-000015 001-000019	REL. NOT REL. REL. NOT REL. REL. NOT REL. REL. NOT REL. REL. NOT 6 (31.6) 0 1 (5.3) 0 0 0 7 (36.8) 0 6 (31.6) 0 1 (5.3) 0 0 0 7 (36.8) 0 6 (31.6) 0 1 (5.3) 0 0 0 7 (36.8) 0 001-000019 001-000017 001-000013 001-000015 001-000019

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